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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,133	12/27/2000	Russell Mumper	50229-207	3309

7590

05/08/2002

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EXAMINER

DEWITTY, ROBERT M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,133

Applicant(s)

MUMPER ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 33-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-62 are pending in the instant application. Receipt is acknowledged of Election of Species and Request for Rescinding mailed 2/22 and 3/16, 2003.

Election/Restrictions

1. Claims 33-62 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Specification

2. The use of the trade-marks Noveon and Carbomer has been noted in this application (see claim 4). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vora et al. (U.S. Pat. No. 5,326,737), further in view of Acharya (U.S. Pat. No. 5,102,666) and Benes et al. (U.S. Pat. No. 5,639,469).

Vora et al. teaches that amlexanox can be used to treat aphthous ulcers and other mucocutaneous disorders in the form of a gel. The dosage forms should slowly release the drug to minimize swallowing of the drug (col. 2, lines 64-67). Pastes forms can include diluents, adhesives, viscosity builders, plasticizers, emulsifiers, flavoring agents, sweetening agents, and other ingredients. However, Vora does not teach using a swellable polymer, and a pH-sensitive polymer in the formulation.

Acharya teaches controlled release compositions containing polycarbophil-type (aka Noveon) component with water in the presence of an active composition. The compositions may be in the form of gels. The water used in the polycarbophil may be mixed with other cosolvents, such as polyethylene glycols or propylene glycol (col. 10, lines 61-65).

Benes et al. teaches delivery of a drug (heparin anticoagulant) across a mucosal surface. It is taught drugs delivered across oral mucosa avoid hepatic first-pass inactivation, poor or erratic absorption from the gastro-intestinal tract, inactivation by gastro-intestinal fluids, and other modes of inactivation characteristic of oral drug ingestion (col. 1, lines 15-20). The device of Benes includes means for adhering to mucosa. The mucosa adhesive comprises a polymeric resin and an elastomeric component (col. 5, lines 24-36). The resin is preferably of the type trade-marked as CARBOPOL (col. 5, lines 66-67). The resin contains carboxylic acid moieties, such as

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Eudragit (col. 5, lines 43-45 and col. 6, line 14). The device of Benes contains less than 10% of the resin, and of the 10%, carboxylic acid moieties is 55% (col. 5, lines 37-45).

Motivation to use a resin such as Carbopol containing carboxylic acid moieties (Eudragit), in a mucoadhesive gel would have arisen because Benes et al. teaches that drugs delivered across the oral mucosa avoid hepatic first-pass inactivation, poor or erratic absorption from the gastro-intestinal tract, inactivation by gastro-intestinal fluids, and other modes of inactivation characteristic of oral drug ingestion, and delivering drugs across the mucosa can be affected using mucoadhesive gel. Whereas the art does not explicitly disclose the use of a pH-sensitive polymer, Eudragit as disclosed in the art, inherently contains such characteristic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Neil Levy can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
May 6, 2002



NEIL S. LEVY
PRIMARY EXAMINER